Ved indlæggelse pga infektion eller GVHD, der vurderes til IKKE at være relateret til studiemedicin -så skal det ikke rapporteres som SAE. Det skal dokumenteres i journalen af lægen, at det ikke er relateret.

4.6.2. Definition of SAEs

An AE is considered "serious" if, in the view of either the investigator or Sponsor, it results in any of the following outcomes:

- Death
- Is life threatening (an AE is considered "life-threatening" if, in the view of either the investigator or Sponsor, its occurrence places the participant at immediate risk of death. It does not include an AE that, had it occurred in a more severe form, might have caused death)
- Persistent or significant disability/incapacity or substantial disruption of the ability to conduct normal life functions
- Congenital anomaly or birth defect
- Requires hospitalization or leads to prolongation of hospitalization (hospitalization for treatment/observation/examination caused by AE is to be considered as serious)
- Other medically important events that may not be immediately life-threatening or result in death/hospitalization, but may jeopardize the participant or may require intervention to prevent one of the other outcomes listed above.

Medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations. These events, including those that may result in

disability/incapacity, should also be considered serious. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalization or development of drug dependency or drug abuse.

For this study, GVHD and infection are only to be reported as SAEs if one of the following conditions is met: 1) the event is both related to study drug and also meets the definition of SAEs above, or 2) the event results in death that occurs within 30 days after the last dose of study drug.

AML relapse will not be reported as an AE/SAE term unless it is the cause of a death that occurs between the first day of study drug though 30 days after the last dose of study drug (inclusive).